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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,262	11/25/2003	Jeffrey E. Fetterman	125889.101	6372

7590 12/02/2008  
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EXAMINER
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RAJ, RAJIV J

ART UNIT	PAPER NUMBER
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3686

MAIL DATE	DELIVERY MODE
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12/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,262	<b>Applicant(s)</b> FETTERMAN ET AL.	
	<b>Examiner</b> RAJIV J. RAJ	<b>Art Unit</b> 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 April 2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Claims**

1. This action is in reply to the election filed on 15 August 2008.
2. Claims 1-42 have been elected.
3. Claims 1-42 are currently pending and have been examined.

### **Priority**

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

### **Information Disclosure Statement**

5. The Information Disclosure Statement filed 16 April 2004 has been considered.  
An initialed copy of the Form 1449 is enclosed herewith.

### **Claim Rejections - 35 USC § 101**

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 1-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent, a method/process claim must (1) be tied to another statutory class of invention

(such as a particular apparatus) (see at least *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (see at least *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972)). A method/process claim that fails to meet one of the above requirements is not in compliance with the statutory requirements of 35 U.S.C. 101 for patent eligible subject matter. Here claims 1-42 fail to meet the above requirements because the limitations are not tied to a statutory class of invention. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. See *Benson*, 409 U.S. at 71-72. As *Comiskey* recognized, "the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter." *Comiskey*, 499 F.3d at 1380 (citing *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir. 1989)). Incidental physical limitations, such as data gathering, field of use limitations, and post-solution activity are not enough to convert an abstract idea into a statutory process. In other words, nominal or token recitations of structure in a method claim do not convert an otherwise ineligible claim into an eligible one.

### **Claim Rejections - 35 USC § 112**

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 15 & 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "*effective*" is vague and indefinite. For the purposes of this examination, the Examiner will interpret "*effective*" as cited in the prior art.

10. As per claim 11 the limitation "*optionally*" is a conditional statement without corresponding "else" statements. If these limitations are not performed, then there is no defined process to be performed. The examiner understands that in these claims, the open conditional language causes these limitations to be omitted.

Processes and system parts can be considered as a series of steps or parts to achieve a claimed task. When executing a process or utilizing a system, each step is performed or part is utilized. However, upon reaching an "IF-THEN-ELSE" logical block, each TRUE/FALSE option is equally likely. A process step, or a system part, that includes only an "IF-THEN" logical question means that THEN result only occurs when the answer is TRUE. An answer equally likely is FALSE and therefore the THEN result will not occur.

The Examiner takes further guidance from the MPEP § 2106(II)C on how to handle these logical blocks. Specifically, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." It is

the Examiner's position that when a claimed invention includes a logical block that suggests another choice (FALSE), then the resulting action is not limiting as it may never be performed.

### **Claim Rejections - 35 USC § 103**

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1, 7-21, 23-25, & 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud (US 2002/0042725 A1) (hereinafter Mayaud) in view of Ghouri (US 2004/0049506 A1) (hereinafter Ghouri) in further view of Applicant's Own Admission (hereinafter AOA).

14. **Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the

convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

**Claim 1**

Mayaud as shown, discloses the following limitations:

- *identifying a medication-use process associated with a pharmaceutical product; (see at least Mayaud [0269-0270] Fig:6 Items:110-120 & related text)*
- *designing a risk management intervention program to manage said adverse events; (see at least Mayaud [0033], Fig:15 Items:182-188 & related text)*

Mayaud does not disclose the following limitations, however Ghouri, as shown does:

- *identifying, characterizing and ranking adverse events caused by using the pharmaceutical product; (see at least Ghouri [0090-0093])*
- *quantifying the potential effect of said failure mode to create a pharmaceutical hazard score, wherein said hazard score considers the*

*severity and frequency of occurrence of the effects of said failure; (see at least Ghouri [0083-0090])*

- *conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; (see at least Ghouri [0083-0090])*

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud. One of ordinary skill in the art would have added this feature into Mayaud with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Applicant's limitation, in claim 1: *to evaluate the need to mitigate the effect of said failure modes;*, is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Dempsey. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Mayaud/Ghouri does not disclose the following limitation, however AOA, as shown does:



- *identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects; (see at least AOA [0002-0006])*

It would have been obvious to one of ordinary skill in the art to add the features of AOA into Mayaud/Ghourri. One of ordinary skill in the art would have added these features into Mayaud/Ghourri with the motivation to provide an improved process for identifying and creating an ideal prescription plan in order to provide improved health care to patients.

#### **Claim 7**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 1. Ghourri further discloses the following limitation:

- *analyzing available data from animal, toxicology, pharmacokinetic, pharmacodynamic and pharmacogenomic studies of the pharmaceutical product; (see at least Ghourri [0019-0020])*

It would have been obvious to one of ordinary skill in the art to add the feature of Ghourri into Mayaud/Ghourri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghourri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghourri Column:3 Lines:10-67 Column:4 Lines:1-42)

#### **Claim 8**

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Ghouri further discloses the following limitation:

- *analyzing existing clinical safety data for the pharmaceutical product;* (see at least Ghouri [0019-0020])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

#### **Claim 9**

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Ghouri further discloses the following limitation:

- *analyzing risks identified in similar products;* (see at least Ghouri [0013, 0019-0020])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

### **Claim 10**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *graphically depicting the medication use process of prescribing, dispensing, and administering the pharmaceutical product as a plurality of steps; (see at least Mayaud Fig:3-15 & related text)*
- *identifying subprocesses for each of said steps; (see at least Mayaud Fig:1-4,6, 15 Items:10, 45, 110 & 182 & related text)*

### **Claim 11**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *identifying one or more processes of prescribing, dispensing or administering the pharmaceutical product or a combination thereof; (see at least Mayaud Fig:3 Items:54-70, 98-102 & related text)*
- *optionally identifying subprocesses of said one or more processes; (see at least Mayaud Fig:1-4,6, 15 Items:10, 45, 110 & 182 & related text)*

### **Claim 12**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 1.

Ghourri further discloses the following limitation:

- *utilizing a pharmaceutical severity scale; and utilizing a pharmaceutical frequency of occurrence scale; (see at least Ghourri Fig:2 & related text)*

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

**Claim 13**

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *analyzing the criticality and detectability of the failure mode to determine the need to mitigate the failure mode; (see at least Mayaud [0240-0241], [0245-0246])*

**Claim 14**

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 13. Mayaud further discloses the following limitation:

- *analyzing existing risk control measures for the failure mode to determine whether they are effective in mitigating the failure mode without further intervention; (see at least Mayaud [0240-0241], [0245-0246])*

**Claim 15**

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 13. Mayaud further discloses the following limitation:

- *effective education, communications and/or control measures in redundant combinations and incorporating adult learning principles designed to be readily implemented in order to effectively reduce the incidence and consequences of said failure modes; (see at least Mayaud [0240-0246])*

#### **Claim 16**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *a primary intervention targeted to reduce the incidence of each failure mode; (see at least Mayaud [0240-0246])*

#### **Claim 17**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *one or more redundant backup interventions to decrease the occurrence of and/or mitigate the consequences of failure of the primary intervention; (see at least Mayaud [0240-0246])*

#### **Claim 18**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *distributing interventions to multiple end users, wherein the multiple end users are selected from the group consisting of physicians, health care*

*providers, caregivers and patients;* (see at least Mayaud [0240-0246]

Fig:16 Items:201-214 & related text)

#### **Claim 19**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *coordinating care among multiple end users, wherein the multiple end users are selected from the group consisting of physicians, health care providers, caregivers and patients;* (see at least Mayaud Fig:16 Items:201-216 & related text)

#### **Claim 20**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *tailoring said risk management intervention program to local medical practice standards and needs including, but not limited to the delegation of primary responsibility for the program from physician to support staff;* (see at least Mayaud [0113-0124])

Examiner notes that all claim language, in claim 20, following *but not limited to* . . . is not given any patentable weight. This claim language fails to further limit or define applicant's invention.

#### **Claim 21**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *designating interventions that are effective in transferring medical knowledge and reinforcing knowledge retention;* (see at least Mayaud [0019-0035] Fig:16 Items:201-216 & related text)

### **Claim 23**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *developing a risk communication curriculum to communicate risk to an end user, wherein the end user is selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients;* (see at least Mayaud Fig:16 Items:201-216 & related text)

### **Claim 24**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *transferring know-how, insights, techniques, methods, and processes from more experienced physicians and support staff to less experienced physicians and support staff;* (see at least Mayaud Fig:16 Items:201-216 & related text)

### **Claim 25**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *utilizing existing interventions and tools developed by one or more of clinicians, peer to peer forums, clinical consultations and preceptorships;*  
(see at least Mayaud Fig:16 Items:201-216 & related text)

### **Claim 29**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *utilizing a professional support network for the collection and management of data associated with the adverse events;* (see at least Mayaud Fig:16 Items:200-218 & related text)

### **Claim 30**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 29.

Mayaud further discloses the following limitation:

- *occurrences of the adverse events;* (see at least Mayaud Fig:16 Items:200-218 & related text)

### **Claim 31**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:



- *educational resources for delivering information regarding prescribing, dispensing, and use of pharmaceutical product;* (see at least Mayaud Fig:3,12,15 Items:138-142,182-188 & related text)

#### **Claim 32**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 31.

Mayaud further discloses the following limitation:

- *identification of control measures for the pharmaceutical product;* (see at least Mayaud [0240-0246])

#### **Claim 33**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 31.

Mayaud further discloses the following limitation:

- *classes to instruct and end user on said control measures;* (see at least Mayaud [0300] Fig:11 & related text)

#### **Claim 34**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 31.

Mayaud further discloses the following limitation:

- *educational resources are available by electronic, written, audio, or video communication;* (see at least Mayaud Fig:16 Items:200-218 & related text)

#### **Claim 35**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *implementing distribution controls wherein said distribution controls manage the availability of the pharmaceutical product;* (see at least Mayaud Fig:16 Items:200-218 & related text)

### **Claim 36**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 35.

Mayaud further discloses the following limitation:

- *limiting availability of the pharmaceutical product to a single source;* (see at least Mayaud [0346-0359], Fig:16 Item:206 & related text)

15. Claims 2-6, 26-27 & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Ghour in view of AOA in further view of Ousdigian et al. (US 6438407 B1) (hereinafter Ousdigian).

### **Claim 2**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Ousdigian further discloses the following limitation:

- *implementing said risk management program;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghour/AOA. One of ordinary skill in the art would

have added this feature into Mayaud/Ghour/AOA with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

### **Claim 3**

The combination of Mayaud/Ghour/AOA/Ousdigian disclose all the limitations of claim 2. Ousdigian further discloses the following limitation:

- *measuring the effectiveness of said risk management program;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghour/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghour/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

### **Claim 4**

The combination of Mayaud/Ghour/AOA/Ousdigian disclose all the limitations of claim 3. Ghour further discloses the following limitation:

- *measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting;* (see at least Ghour Fig:2 & related text)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghourri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghourri/AOA/Ousdigian with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghourri Column:3 Lines:10-67 Column:4 Lines:1-42)

**Claim 5**

The combination of Mayaud/Ghourri/AOA/Ousdigian disclose all the limitations of claim 3. Ghourri further discloses the following limitation:

- *integrating said effectiveness measurement into said pharmaceutical product hazard score; (see at least Ghourri [0076-0087], [0090-0094])*

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghourri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghourri/AOA/Ousdigian with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghourri Column:3 Lines:10-67 Column:4 Lines:1-42)

**Claim 6**

The combination of Mayaud/Ghourri/AOA/Ousdigian disclose all the limitations of claim 5. Ousdigian further discloses the following limitation:

- *reporting said effectiveness measurement;* (see at least Ousdigian Column:2 Lines:16-28)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghourri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghourri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

#### **Claim 26**

The combination of Mayaud/Ghourri/AOA disclose all the limitations of claim 1. Ousdigian further discloses the following limitation:

- *implementing human behavior changing interventions;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghourri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghourri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

#### **Claim 27**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Ousdigian further discloses the following limitation:

- *utilizing disease management approaches, principles, methods, techniques and tools to change end user behavior; (see at least Ousdigian Column:2 Lines:9-64)*

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghour/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghour/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

#### **Claim 41**

The combination of Mayaud/Ghour/AOA disclose all the limitations of claim 1.

Ousdigian further discloses the following limitation:

- *mandating periodic or intermittent tests for the existence of contraindications for the pharmaceutical product; (see at least Ousdigian Column:2 Lines:9-64)*

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghour/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghour/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical

plan and more effectively administer an individually tailored medical regimen.

(see at least Ousdigian Column:2 Lines:4-64)

16. Claims 22, 28 & 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Ghouri in view of AOA in further view of Official Notice.

**Claim 22**

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 1. The combination of Mayaud/Ghouri/AOA does not specifically disclose *utilizing one or more of adult learning principles, enablers, personal application, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when administering an effective health program. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *utilizing one or more of adult learning principles, enablers, personal application, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages* because such practices are standard and necessary aspects of implementing any type of health assessment program.

**Claim 28**

The combination of Mayaud/Ghour/AOA discloses all of the limitations of claim 1. The combination of Mayaud/Ghour/AOA does not specifically disclose *integrating risk messages into promotional materials of the pharmaceutical product*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghour/AOA with *integrating risk messages into promotional materials of the pharmaceutical product* because such practices are standard and necessary to conform to the requirements of distributing pharmaceutical products.

### **Claim 37**

The combination of Mayaud/Ghour/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghour/AOA does not specifically disclose *limiting availability of the pharmaceutical product to authorized pharmacies*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghour/AOA with *limiting availability of the pharmaceutical product to authorized pharmacies* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.



**Claim 38**

The combination of Mayaud/Ghour/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghour/AOA does not specifically disclose *requiring a pharmacist to be certified to dispense the pharmaceutical product*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghour/AOA with *requiring a pharmacist to be certified to dispense the pharmaceutical product* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

**Claim 39**

The combination of Mayaud/Ghour/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghour/AOA does not specifically disclose *limiting physician prescribing rights*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghour/AOA with *limiting physician prescribing rights* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

**Claim 40**

The combination of Mayaud/Ghourri/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghourri/AOA does not specifically disclose *limiting the number of refills per prescription, limiting the expiration date of a prescription, and/or limiting the form of a prescription*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghourri/AOA with *limiting the number of refills per prescription, limiting the expiration date of a prescription, and/or limiting the form of a prescription* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

Claim 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Ghourri in view of AOA in view of Ousdigian in further view of Official Notice.

**Claim 42**

The combination of Mayaud/Ghourri/AOA/Ousdigian discloses all of the limitations of claim 41. The combination of Mayaud/Ghourri/AOA/Ousdigian does not specifically disclose *contraindications comprise pregnancy*. However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to

employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghourri/AOA/Ousdigian with *contraindications comprise pregnancy* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **(571) 270-3930**. The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor** can be reached at **571.272.6787**.

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